REMARKS

Enablement Rejection

Claim 14 was rejected under 35 USC § 112, first paragraph, on the asserted grounds that the claim fails to comply with the enablement requirement. (Paper No. 9[1] at 3.)

For the reasons set forth below, the rejection, respectfully is traversed.

In making the rejection, the Examiner asserted that "[c]laim 14 is drawn to a process of lowering cholesterol and triglyceride levels in a mammal do not have complete support in the specification. There is no mention of 'process' anywhere in the disclosure for the process of lowering of cholesterol and triglyceride." (Paper No. 9 at 4.) The Examiner concluded that "[t]here are no working examples for the process as claimed in claim 14. Since no guidance is provided in the disclosure one skilled in the art would not be able to practice the invention without undue experimentation." (*Id.*)

As is well settled, it is the Examiner's burden to demonstrate that a specification is not sufficiently enabling. *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). To carry this burden, the Examiner must identify and clearly articulate the factual bases and supporting evidence that allegedly establish that undue experimentation would be required to carry out the claimed invention. *Id.* at 370.

Here, the Examiner has simply posited, in conclusory fashion, that "a process of lowering cholesterol and triglyceride levels in a mammal do not have complete support" and that "[t]here is no mention of 'process' anywhere in the

[1] The outstanding Office Action is denoted as Paper No. 8 on the cover sheet, and as Paper No. 9 on the Office Action Summary. For purposes of clarity, the outstanding Office Action is referred to as Paper No. 9 throughout this Response.

disclosure for the process of lowering cholesterol and triglyceride." (*Id.* at 4.) The Examiner further asserted that "[t]here are no working examples for the process as claimed in claim 14." (*Id.*)

It is respectfully submitted that the rejection is predicated on a number of factual errors and, therefore, must be withdrawn. The first factual error is the Examiner's assertion that:

> [t]here is no mention of 'process' anywhere in the disclosure for the process of lowering cholesterol and triglyceride.

On page 4, lines 15-18, of the specification a process for lowering serum cholesterol and triglyceride levels in a human is expressly described:

> A process for lowering serum cholesterol and triglyceride in a mammal is also another object of the invention. This process includes administering to the mammal an effective amount of a phytosterol and/or a phytostanol ester compound as defined above in combination with a pharmaceutically acceptable carrier.

Moreover, on page 12, lines 21-30, the specification describes how to administer compositions of the present invention to reduce serum cholesterol and triglyceride levels:

> The compounds of the present invention may be administered to any mammal requiring reduction of serum cholesterol and triglycerides. In the present invention, humans are preferred examples of mammals.
>
> ***A compound of the present invention may be administered to e.g., a human by any convenient process***, such as, for example, orally, nasally, IV, IP, anally, etc. An effective amount of a compound according to the present invention will vary based on a number of well known factors including the form of the compound used, the weight of the patient, and the route of administration. Thus, an effective amount of a composition according to the present invention may be readily determined by one skilled in the art

> using known dosing techniques and the data presented in the examples below. (Emphasis added.)
>
> The second factual error is the Examiner's assertion that:
>
> [t]here are no working examples for the process as claimed in claim 14.

On pages 5-12 of the specification an example is provided which demonstrates that rats fed a diet containing a composition within the scope of claim 14 had lowered serum cholesterol and triglyceride levels. *See* Tables 3 and 5.

Thus, the rejection is factually incorrect in at least two aspects – there is a description of the claimed process and there is a working example demonstrating the lowering of serum cholesterol and triglyceride levels in a mammal administered a composition as claimed. Because the rejection is factually flawed, it cannot stand and must be withdrawn.

Rejections under 35 USC § 103

Claims 9-14 were rejected under 35 USC §103(a) as being unpatentable over Higgins, III, U.S. Patent No. 5,892,068 ("Higgins") and Higashidate *et al.*, J. of Chromatography, 515, pp. 295-303 (1990) ("Higashidate"). (Paper No. 9 at 4-5.)

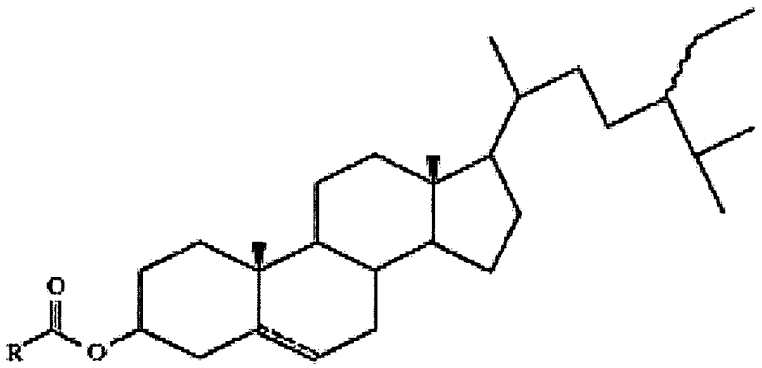
For the reasons set forth below the rejection, respectfully is traversed.

Higgins discloses the preparation of discrete stanol and stanol-esters through an acid catalyzed reaction. (Column 1, lines 5-7.) In the reaction, a stanol or sterol is esterified with a fatty acid. (Column 1, line 66 - column 2, line 1.)

The fatty acids used in the reaction are broadly defined to include those fatty acids defined by the general formula:

CH_3–$(CH_2)_n$–CO_2H wherein n is an integer from 4 to 20. (Column 2, lines 6-8.)

Likewise, the sterol and stanol esters are broadly defined by Higgins in FIG. 1:



(*Id.*, lines 16-30.) β-sitosterol is exemplified as a sterol within the scope of the disclosure. (*Id.*, lines 51-52.)

Higgins discloses that the two isolation methods provide yields of ester in excess of 95%, such as for example, providing a single stanol (sterol) ester, with less than 0.2 weight percent of other ester products. (See, column 3, line 25 - column 4, line 4.) In the Examples, Higgins discloses the production of β-sitostanol stearate (Examples 1 and 2), β-sitostanol palmitate (Example 3), β-sitostanol oleate (Example 4), cholestanol oleate (Example 5), and a mixture of stanol-oleate, stanol-linoleate, stanol-linolenate, and stanol-palmitate (Comparative Example).

Higashidate discloses a method of isolating methyl esters of eicosapentaenoic acid ("EPA") and docosahexaenoic acid ("DHA"). (Page 302.) Higashidate discloses a two-step method for the "enrichment" of EPA and DHA from esterified fish oil. (*See* Abstract and page 297.) In the first step, EPA and DHA were extracted from an esterified fish oil sample using supercritical fluid extraction ("SFE")

with carbon dioxide. (Page 297.) When the extraction was complete, supercritical fluid chromatography ("SFC") with carbon dioxide was performed to further purify the EPA and DHA fractions. (*Id.*)

The SFC was performed on a silica gel column coated with silver nitrate. (Pages 296 and 297.) Higashidate observes that using a silica gel coated with silver nitrate was expected to be advantageous in the SFC process given its known function in liquid chromatography ("LC") applications.

> In LC, it is known that a silica gel column coated with silver nitrate is very suitable for separation of alkenes with *cis* configurations from *n*-alkanes, because *cis*-alkenes form silver chelates that are adsorbed on the stationary phase more strongly than *n*-alkanes. The use of this technique for the concentration of esters of EPA and DHA has been reported. If the compounds behave in the same way in supercritical carbon dioxide mobile phase, then SFC using a silver nitrate-coated silica gel column can enrich EPA and DHA esters efficiently. Such a separation system will have the advantages of both SFE and LC. (citations omitted) (Page 296.)

Higashidate also observes that direct injection of esterified fish oil was "unsuccessful" because of precipitation problems that led to a decrease in column selectivity.

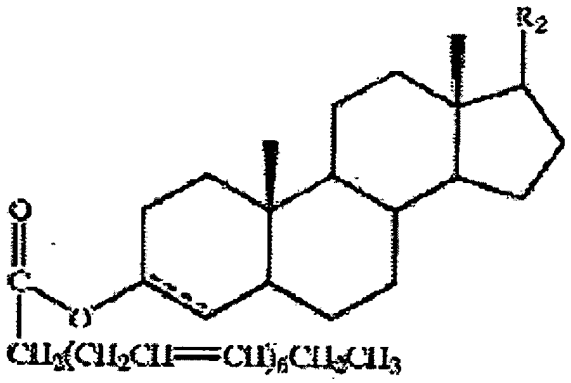
> However, direct injection of the esterified fish oil was unsuccessful in this fractionation, because constituents of the esterified fish oil insoluble in supercritical carbon dioxide precipitated and covered the stationary phase, resulting in a decrease in the selectivity of the column. (Page 297.)

Higashidate concludes that the disclosed method results in "enrichment" of the amount of EPA and DHA methyl esters in the column fractions, to *e.g.*, 93% and 82%, respectively. (Pages 298 and 302 (Table I).)

In making the rejection, the Examiner asserted that "[t]he references teach stero/stanol esters of poly unsaturated fatty acids and methyl esters of

docosahexaenoic acid (DHA), which embrace instantly, claimed invention." (Paper No. 9 at 5.) The Examiner then pointed to specific disclosure in Higgins:

> See the entire documents especially lines 54-62 in col. 1; lines 6-15, col. 2 in US '068. See also claim 1 and examples for the method of preparation of sterol esters. This composition is specifically taught by U.S. '068 (lines 14 in col. 2).



β-sitosterol docosahexaenoate; and
β-sitostanol docosahexaenoate

(*Id.*) "See abstract and first Para on page 295, Table 1 and last two paragraphs on page 302 in Higashidate reference." (*Id.*)

The Examiner acknowledged, however, that the "[i]nstant claims differ from the reference in claiming nutritional supplement of specific sterol esters from C18 to C22 having at least three double bonds whereas [Higgins discloses] sterol esters with unsaturated fatty acids, example given contains at least three double bonds (DHA) which is the same as one of the instantly claimed sterol ester i.e. sterol with DHA, sitosterol docosahexaenoate and sitostanol docosahexaenoate." (*Id.*)

To fill the acknowledged gap, the Examiner asserted that "[s]ince Higgins teaches such sterol esters and Higashidate teaches that fish oil contains omega-3 fatty acids (a class of PUFA) which includes docosahexaenoic acid (DHA) and eicosahexaenoic acid[2] (EPA), one would find ample motivation to prepare sterol esters with unsaturated fatty acids from active compounds present in fish oil ...." (*Id.* at 6.)

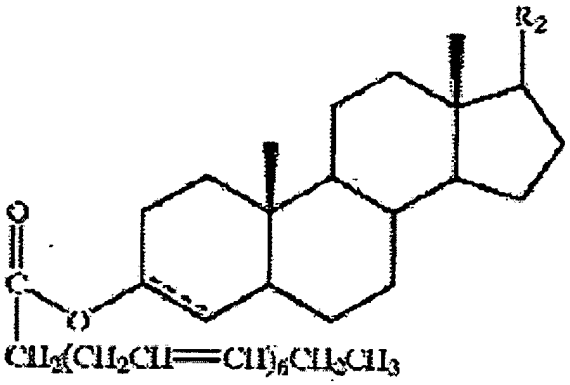
The Examiner concluded that "it would have obvious ... to prepare additional beneficial nutritional supplement using sterols with a pendent ester functionality which when hydrolyzed provides another cholesterol-lowering agent." (*Id.*)

Initially we note, the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

As is well settled obviousness must be based upon facts, "cold hard facts." *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970). Absent such factual support a rejection must fail. Because the rejection is factually inadequate, it must be withdrawn for this reason also.

The Examiner asserted that Higgins discloses a specific compound at column 2, line 14:

[2] We note that the Examiner used the term "eicosahexaenoic acid" but indicates that the compound is abbreviated EPA. We assume that the Examiner intended eicosapentaenoic acid when eicosahexaenoic acid was written in conjunction with the discussion of Higashidate. If this assumption is incorrect, the Examiner is requested to clarify this issue on the record.



β-sitosterol docosahexaenoate; and
β-sitostanol docosahexaenoate

However, this compound is not found anywhere in Higgins.[3] At column 2, line 14 Higgins reads "... include oleic, linoleic, docosohexanoic acid and ..." No structure at all is disclosed. None of the three structures found in Higgins is the structure cited by the Examiner. *See* col. 2, lines 20-30 and lines 40-50 and claim 1. Moreover, Higgins discloses only four specific esters: β-sitostanol stearate (Examples 1 and 2), β-sitostanol palmitate (Example 3), β-sitostanol oleate (Example 4), and cholestanol oleate (Example 5). Thus, contrary to the Examiner's assertion β-sitosterol docosahexaenoate and β-sitostanol docosahexaenoate are not disclosed in Higgins.

Because the rejection is based on the wrong reference and relies on facts not in evidence, the rejection is factually deficient and must be withdrawn for this reason alone.

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[3] The Examiner appears to have confused Higgins with the related Higgins, III, U.S. Patent No. 6,147,236 ("'236 patent"). The '236 patent discloses the structure and compounds cited by the Examiner. *See* Col. 4, line 56 - col. 5, line 14. We note, however, the '236 patent is ***not*** prior art to the present application for the reasons presented in our previous response dated May 13, 2003. The Examiner apparently found that

Moreover, the rejection fails to identify why one skilled in this art would modify the disclosure of Higgins using Higashidate to arrive at the claimed invention. Higgins discloses a method of direct esterification of stanols and sterols. Higashidate discloses the separation of DHA and EPA methyl esters from esterified fish oil.

Nowhere in Higashidate is there any disclosure of the esterification of any compound. Higashidate is concerned solely with the separation of DHA and EPA methyl esters from esterified fish oil. No esterification of the fish oil is disclosed or suggested. The only esters even disclosed in Higashidate are methyl esters of DHA and EPA. There is no disclosure or suggestion of any ester of a sterol or stanol in Higashidate. Moreover, there is no disclosure or suggestion of any use for the isolated methyl esters of DHA and EPA. Higashidate merely discloses the separation of the compounds, and no use of or composition containing them is disclosed or suggested.

We also note that Higgins discloses processes that provide "discrete" sterol and stanol esters with yields approaching 100% (i.e., "less that 0.2 percent of the other ester products"). (*See* column 4, lines 2-4.) The Examiner failed to identify any suggestion or motivation that would lead one to combine Higashidate with Higgins when yields of the Higgins esters are close to 100%.

Nor did the Examiner identify any suggestion or motivation to substitute the two specific fatty acids disclosed in Higashidate for the generically disclosed C_{6-22} fatty acids disclosed in Higgins.

At bottom, the Examiner has provided no evidence why one would be led to combine the esterification process of Higgins with the separation technique of

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argument persuasive because no rejection based on the '236 patent is presented in the outstanding Office

Higashidate. Accordingly, the Examiner has pointed to no evidence or technical reasoning why one would be led to combine Higgins and Higashidate in the manner suggested. That, however, was her burden. Having failed to meet this burden the rejection is deficient and must be withdrawn.

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO must include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the documents relied on by the Examiner as evidence of obviousness. *McGinley v. Franklin Sports*, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). The factual inquiry whether to combine documents must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion to combine "must be based on objective evidence of record." *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002).

The rejection concludes that "it would have obvious ... to prepare additional beneficial nutritional supplement using sterols with a pendent ester functionality which when hydrolyzed provides another cholesterol-lowering agent." (Paper No. 5 at 6.) However, an "additional beneficial nutritional supplement using sterols with a pendent ester functionality which when hydrolyzed provides another cholesterol-lowering agent" is not what is claimed. Claim 9 recites a composition containing "a pharmaceutically acceptable carrier in combination with an effective amount of phytosterol and/or phytostanol ester...." Accordingly, the Examiner rejected subject matter which has not been claimed. Moreover, claim 14 is a "process for lowering serum cholesterol and triglycerides levels in a mammal...." The rejection is

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Action. Moreover, the '236 patent has ***not*** been cited in the Office Action and is ***not*** part of the rejection.

absolutely silent as to any process much less the claimed process. Because the rejection does not reject that which is claimed, it is both legally and factually deficient and must be with drawn.

Claims 9-14 were rejected under 35 USC § 103 as unpatentable over Mitchell, U.S. Patent No. 4,588,717 ("Mitchell"), Mishkel *et al.*, Baillière's Clinical Haematology, Vol. 3, No. 3, pp. 625-649 (1990) ("Mishkel"), and Kamarei *et al.*, U.S. Patent No. 4,879,312 ("Kamarei"). (Paper No. 9 at 6.)

For the reasons set forth below the rejection, respectfully is traversed.

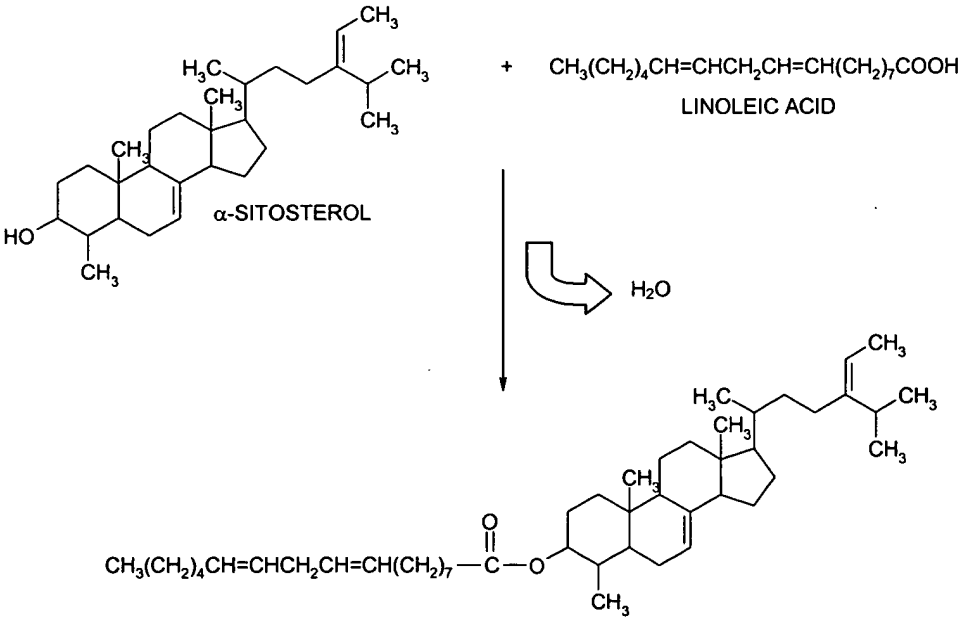
Mitchell discloses a broad range of vitamin supplements containing phytosterol esters, substituted fructose compounds and antitrypsin enzymes, as well as, methods of making same. (Column 1, lines 7-12.) The disclosed phytosterol ester supplements were designed to provide a method for administering steroids and hormones to humans and other animals without directly introducing the hormones and steroids into the blood stream or digestive tract, which would have undesirable effects, including androgenic effects, acne, voice changes, poor absorption, and the generation of toxic byproducts when in the digestive tract, *etc.* (*Id.*, lines 46-65.)

Mitchell broadly discloses fatty acid esters of phytosterols, such as sitosterol, stigmasterol, taraxasterol and mixtures thereof. (Column 3, lines 26-36 and column 5, lines 48-51.) Mitchell broadly defines the phytosterol portion of the disclosed esters to include "all phytosterols" and derivatives thereof. (Column 5, lines 26-28.)

Mitchell defines the fatty acid portion of the disclosed esters to include "***any*** fatty acid having from about 18 to about 20 carbon atoms in the main carbon chain and at least two carbon-to-carbon double bonds in addition to terminal carboxyl and

methyl groups." (emphasis added.)(Column 6, lines 2-8.) Mitchell recognizes that "many fatty acids are included within this category." (*Id.*) In preferred embodiments, Mitchell identifies linoleic acid (C_{18}, ω-6-fatty acid), linolenic acid (C_{18}, ω-3-fatty acid) and archidonic acid (C_{20}, ω-6-fatty acid) as the fatty acid source of the phytosterol esters. (Column 3, lines 26-36.) Mitchell further includes fatty acids having less than 18 carbon atoms and more than 20 carbon atoms within the scope of the invention, but notes that phytosterol esters made with such fatty acids "tend to have less utility in achieving the purposes of the present invention" (*i.e.*, delivering steroid and hormone precursors to the body). (Column 6, lines 9-15.)

Mitchell describes the reaction between a phytosterol and a fatty acid as a "condensation" reaction and provides a characteristic reaction scheme, which is said to be "essentially the same" reaction between "any given phytosterol" and "any given fatty acid."



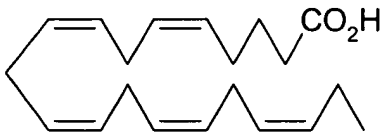
LINOLEIC ACID ESTER OF α-SITOSTEROL

(*See* Column 8, lines 33-37 and Equation 1.)

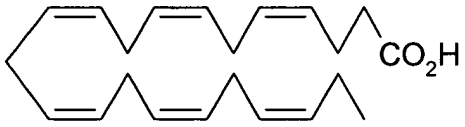
Mitchell provides 75 examples of the phytosterol ester vitamin supplement. In those examples, however, only three different fatty acids are exemplified as part of the phytosterol ester - linoleic acid (Examples 1-25), linolenic acid (Examples 26-50) and arachindonic acid (Examples 51-75). Likewise, in the 75 examples, only three phytosterols are exemplified as the phytosterol component of the ester - sitosterol, stigmasterol and taraxasterol.

Mishkel is a chapter from a clinical hematology textbook. The "purpose of this chapter is to review the salient studies of fish oils and their application to human cardiovascular disease." (Abstract.) Mishkel also discloses that fish oil and omega-3 fatty acids appear to have beneficial effects on cardiovascular health. *See e.g.*, pp. 626, 1st ¶ and 628, 2nd ¶.

Kamarei discloses a "method for provoking or enhancing" the formation of new blood vessels, a process called "angiogenesis," in a patient by administering "an angiogenically effective amount of an angiogenically active ω-3 polyunsaturated fatty acid." (Column 3, lines 13-17.) Kamarei discloses that "preferred" ω-3 polyunsaturated fatty acids are EPA and DHA. (*Id.*, lines 18-19.) Kamarei sets forth the chemical structures of EPA and DHA in Fig. 1:



EPA



DHA

Kamarei discloses that a diet rich in *ω*-3 fatty acids has a beneficial effect in humans, including reduction of plasma cholesterol and triglyceride levels. (Column 2, lines 39-41.) Kamarei also observes that EPA reportedly was known to reduce triglyceride levels and very low density lipoprotein ("VLDL") serum levels. But, when administered to a patient, EPA caused bleeding time to increase and the ability of platelets to aggregate to decrease. (*Id.*, lines 54-59.) Kamarei also discloses that it was known to use of a combination of one of EPA and DHA and a linoleic acid derivative in the treatment of thrombo-embolic conditions. (*Id.*, lines 63-68.) Kamarei

also discloses that it was known to administer mixtures of EPA and DHA/linoleic acid derivatives in food form. (Column 3, lines 2-5.)

In making the rejection, the Examiner asserted that Mitchell discloses "vitamin supplements containing phytosterol esters such as fatty acid esters of sterol, stigmasterol and taxasterol, in various combinations, a composition of the phytosterols, such as sitosterol, stigmasterorl, taraxasterol etc. reacted with polyunsaturated fatty acids such as linoleic acid, (18 carbons, two double bonds), linoleic acid (18-carbons, 3-double bonds), arachidonic acid (20-carbons, two double bonds)." (Paper No. 9 at 6-7.) The rejection further asserted that Mitchell discloses the "[f]atty acid may have about 18-20 in addition to two carbon atoms of terminal carboxyl and methyl groups and at least two double bonds such as arachidonic acid, linoleic acid and linolenic acids are used to make phytosterol esters...." (Citations omitted.)(*Id.* at 7.) The Examiner also asserted that Mitchell discloses that "the reaction between any given phytosterol and any given fatty acid is essentially the same and is characterized in equation 1 using sitosterol and linoleic acid as an exemplary fatty acid." (*Id.*)

The Examiner asserted that Mishkel discloses that "fish oil containing omega-3 fatty acids lower the serum and cholesterol levels, and their beneficial effect on preventing and treating cardiovascular disease. See 1st Para on page 626, third paragraph on page 629, second Para on page 628. See also last three paragraphs on page 632, Figure 3 on page 630." (*Id.*)

The Examiner asserted that Kamarei discloses "that a diet rich in omega-3-fatty acids has beneficial effects in humans...." (*Id.*) The rejection also asserted that Kamarei discloses that "one of n-3 PUFA i.e. EPA and DHA reduces triglyceride and

very low-density lipoprotein (VLDL) serum levels and reduces whole blood viscosity." (*Id.* at 8.)

The Examiner acknowledged, however, that "the instant claims differ from the reference in claiming a nutritional supplement of phytosterol ester with specific fatty acids i.e. containing at least 3 double bonds from *C18 to C22* such as docosahexaenoic acid, where [Mitchell discloses] phytosterol ester with fatty acids especially containing poly unsaturated fatty acid approximately *2-22 carbon atoms*." (*Id.*)

To fill the acknowledged gap, the Examiner relied on Mishkel as disclosing "that polyunsaturated fatty acids from fish oil is used to preventing and treating cardiovascular disease" and "two major biologically active fish oil compounds, EPA and DHA." (*Id.*) In addition, the Examiner relied on Kamarei as disclosing that "n-3 PUFA i.e. eicosapentaenoic acid (EPA) and DHA reduces triglyceride and very low-density lipoprotein (VLDL) serum levels and reduces whole blood viscosity." (*Id.*)

The Examiner concluded that "it would have been obvious ... to prepare additional beneficial nutritional supplement using sterols with a pendent ester functionality which when hydrolyzed provides another cholesterol-lowering agent." (*Id.*)

As previously noted, the Examiner bears the burden to set forth a *prima facie* case of unpatentability, and if the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

The rejection concludes that "it would have been obvious ... to prepare additional beneficial nutritional supplement using sterols with a pendent ester functionality which when hydrolyzed provides another cholesterol-lowering agent." (Paper No. 9 at 8.) As noted above, an "additional beneficial nutritional supplement

using sterols with a pendent ester functionality which when hydrolyzed provides another cholesterol-lowering agent" is not what is claimed. Claim 9 recites a composition containing "a pharmaceutically acceptable carrier in combination with an effective amount of phytosterol and/or phytostanol ester...." Accordingly, the Examiner rejected subject matter which has not been claimed. Moreover, claim 14 is a "process for lowering serum cholesterol and triglycerides levels in a mammal...." The rejection is absolutely silent as to any process much less the claimed process. Because the rejection does not reject that which is claimed, it is both legally and factually deficient and must be with drawn.

The rejection also fails to identify why one skilled in this art would combine the disclosures of Mitchell, Mishkel, and Kamarei in the manner suggested to arrive at the claimed invention. Mitchell discloses phytosterol ester compounds and their use in vitamin supplements. Mishkel discloses that fish oil and omega-3 fatty acids are beneficial to cardiovascular health. And, Kamarei discloses a method of causing or increasing angiogenesis by administering effective amounts of omega-3 fatty acids.

Nothing in Mishkel or Kamarei discloses or suggests the esterification of any compound, much less a phytosterol. Mishkel and Kamarei merely disclose that omega-3 fatty acids are useful in treating and preventing cardiovascular disease. Neither Mishkel nor Kamarei discloses or suggests the esterification of these compounds. That omega-3 fatty acids are beneficial to cardiovascular health would not lead one to conclude that these compounds need to be esterified or in any other way mutated. Mishkel and Kamarei disclose that these compounds are effective in their natural, unaltered state.

Accordingly, there is nothing in the cited documents, and the Examiner has offered no evidence or technical reason, why one would be led combine the cited references as suggested. The Examiner has failed to meet the burden to present a *prima facie* for obviousness. For this additional reason, the rejection is deficient and must be withdrawn.

Notwithstanding the forgoing, even if the combination of the cited documents is proper, which is not conceded, Mitchell, Mishkel, and Kamarei, even in combination, do not teach the claimed invention. Mitchell discloses phytosterol esters in vitamin supplements. Mishkel and Kamarei disclose the beneficial effects of omega-3 fatty acids. In combination, the cited documents, at best, suggest the admixture of the phytosterol esters of Mitchell with omega-3 fatty acids in a vitamin supplement. That, however, is not what is claimed. Accordingly, even in combination, Mitchell, Mishkel, and Kamarei do not disclose or suggest the claimed composition. For this reason too, the rejection is deficient and must be withdrawn.

Accordingly, for the reasons set forth above, withdrawal of the rejections and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on March 1, 2004.

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Respectfully submitted,

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